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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/841,741	04/25/2001	Peter Lind	00204RegUS/PHRM-0440	3271

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COZEN O ' CONNOR, P.C.
1900 MARKET STREET
PHILADELPHIA, PA 19103-3508

EXAMINER	
ULM, JOHN D	

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 11/17/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

KC

Office Action Summary	Application No.	Applicant(s)	
	09/841,741	LIND ET AL.	
	Examiner	Art Unit	
	John D. Ulm	1646	

-- The MAILING DATE of this communication app ars on th cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 August 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-33 and 35-87* is/are pending in the application.

4a) Of the above claim(s) *1-29 and 36-79* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *30-33 35 80-87* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

1) Claims 1 to 33 and 35 to 87 are pending in the instant application. Claims 30, 32, 33 and 35 have been amended, claim 34 has been canceled and claims 80 to 87 have been added as requested by Applicant in the correspondence filed 18 August of 2003.

2) Any objection or rejection of record that is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

3) The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4) Claims 1 to 29 and 36 to 79 stand withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 13.

6) Claims 30 to 33 and 35 to 87 are rejected under 35 U.S.C. § 101 because they are drawn to an invention with no apparent or disclosed specific and substantial credible utility for those reasons of record in section 6 of the previous office action. As essentially stated therein, the instant claims are directed to an isolated protein identified therein as "nGPCR-2644". The instant application does not disclose a specific biological role for this protein or its significance to a particular disease, disorder of physiological process which one would wish to manipulate for a desired clinical effect.

Applicant has traversed this rejection on the premise that a polypeptide of the instant invention has a specific utility in the identification of ligands thereto. This is not persuasive because, as stated in the original rejection, whereas one could readily employ a putative receptor

protein of the instant invention in an assay to identify ligands thereto the information obtained thereby would be of little use until one discovers the identity of those physiological processes moderated by that putative receptor".

Applicant has further traversed this rejection on the premise that a protein encoded by the claimed polynucleotide can be employed as a tissue marker for brain, heart, kidney, peripheral blood leukocytes, lung and testis and the employment of that protein as a tissue marker is a credible, specific and substantial utility.

The employment of a protein of the instant invention as a tissue specific marker is not a substantial or specific utility. All human proteins can invariably be classified into two categories, those which are expressed in a tissue or developmentally specific manner and those which are expressed ubiquitously. It can be alleged that any protein which is expressed in a tissue specific manner can be employed to detect the tissue in which it is expressed in a sample. Alternately, a human protein which is expressed ubiquitously can be employed to detect the presence of any human tissue in a sample. Such utilities are analogous to the assertion that a particular protein can be employed as a molecular weight marker, which is neither a specific or substantial utility. One could just as readily argue that any purified compound having a known structure could be employed as an analytical standard in such processes as nuclear magnetic resonance (NMR), infrared spectroscopy (IR), and mass spectroscopy as well as in polyacrylamide gel electrophoresis (PAGE), high performance liquid chromatography (HPLC) and gas chromatography. None of these processes could be practiced without either calibration standards

having known molecular structures or, at least, a range of molecular weight markers having known molecular weights. One could further extrapolate upon this premise by asserting that any item having a fixed measurable parameter can be employed to calibrate any machine or process which measures that parameter. For example, any item having a constant mass within an acceptable range can be employed to calibrate a produce scale in a grocery store. The calibration of produce scales is certainly an important function since most states require produce scales to be calibrated and certified, Therefore, to accept Applicant's arguments that any protein of human origin is useful as a marker would be comparable to conceding that any object of fixed mass has *prima facie* utility as a weight standard. irrespective of any other properties possessed by that object.

It was just such applications that the court appeared to be referring to when it expressed the opinion that all chemical compounds are "useful" to the chemical arts when this term is given its broadest interpretation (*Brenner v. Manson*, 148 U.S.P.Q. 689 (Sus. Ct, 1 966)). Because the steroid compound which was the subject of that decision had a known structure and molecular weight it could have readily been employed as a molecular standard at that time. Further. because that compound was a hydrocarbon it certainly could have been employed in the well known process of combustion for purposes of lighting and/or the generation of heat. The generation of heat by combustion of hydrocarbons certainly was and remains an important process. Irrespective of such obvious utilities. the court still held that the compound produced by the process at issue in *Brenner v. Manson* did not have a specific and substantial utility.

To grant Applicant a patent encompassing an isolated, naturally occurring human protein of as yet undetermined biological significance would be to grant Applicant a monopoly "the metes and bounds" of which "are not capable of precise delineation". That monopoly "may engross a vast, unknown, and perhaps unknowable area" and "confer power to block off whole areas of scientific development, without compensating benefit to the public" (Brenner v. Manson, ibid). To grant Applicant a patent on the claimed polypeptide based solely upon an assertion that it can be employed as a tissue marker is clearly prohibited by this judicial precedent since the compensation to the public is not commensurate with the monopoly granted and would be no different than granting a patent on the process disputed in Brenner v. Manson on the premise that the steroid produced thereby was useful as an analytical standard or as a combustible fuel source.

Applicant has also traversed this rejection on the apparent premise that membership in the G protein-coupled receptor family is, alone, sufficient to establish a utility for a specific protein and, therefore, an assay which employs that protein. Applicant asserts that a protein of the instant invention belongs to a family of proteins of which some members are the targets of "nearly" 350 therapeutic agents currently on the market. This number is actually higher since a number of agents such as antidepressants and hypertension medications were being employed clinically before their site of action was known. However, each clinical agent which has been developed by measuring its interaction with a specific G protein-coupled receptor was evaluated against a receptor whose native ligand and physiological function were known such as the adrenergic receptors, the dopamine receptors and the serotonin receptors. There are also numerous G

protein-coupled receptors such as odorant receptors and calcium sensing receptors which do not appear to mediate any clinically significant process. More importantly. an artisan knew. before they employed a specific G protein-coupled receptor to identify clinically useful compounds, which physiological process or processes they wished to manipulate and that the protein employed in their assay had an influence of that process. Even if one identifies an agonist or antagonist for a receptor of the instant invention by employing the claimed method, this information is useless since one has no idea of what clinical effect the administration of that agonist or antagonist to an individual would have.

Applicant's reference to issued patents describing G protein-coupled receptors as establishing a patentable utility for the claimed nucleic acid is not persuasive because each application is examined on its own merits. In the decision of *In re Hutchison*, 69 USPQ 138 (CCPA, l 946), the court held that "We are not concerned, of course, with the allowed claims in either the patent or in this application. The sole question for our determination is whether the six article claims on appeal were properly rejected below, and this we pass upon without further reference to, and without comparing them with the claims in the patent or the claims which stand allowed in this application." In essence, the position in the instant application that each application is examined on its own merits can be found in the judicial precedent cited above. The rejections in the instant application will only be withdrawn if they are shown to be legally or factually unsound. The fact that a patent may have issued under a different fact situation or in

error does not relieve the USPTO from the responsibility of preventing the reoccurrence of such errors wherever possible.

6) Claims 30 to 33 and 35 to 87 are rejected under 35 U.S.C. § 112. first paragraph, as failing to adequately teach how to use the instant invention for those reasons given above with regard to the rejection of these claims under 35 U.S.C. § 101.

7) Claims 85 to 87 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention and as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention. These claims encompass a polypeptide encoded by a "non-coding" polynucleotide which hybridizes to SEQ ID NO:1. No such polypeptide is described in the instant specification and the specification fails to provide the guidance needed to produce such a polypeptide.

8) Claims 30 to 33 and 80 to 87 are rejected under 35 U.S.C.§ 112. second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

8.1) Claim 30 is vague because it is unclear if the word "thereof" is referring to the "isolated polypeptide" or "SEQ ID NO:2". Claims 31, 35, 83 and 84 are vague in so far a they depend from claim 30 for this element.

8.2) Claims 32, 33, 80, 81 and 82 are confusing because they employ the terms "% homologous and "% sequence identity" in similar capacities. If these terms are interchangeable then Applicant should only employ only a single specific term in the claims to avoid confusion. If these terms are not interchangeable then it is unclear how they differ.

8.3) Claim 85 to 87 are vague and indefinite because the limitation "stringent conditions" is conditional and no single set of defining hybridization conditions is recited in the claims or the specification. The description of this limitation on page 10 of the instant specification is vague because it employs qualifying terms such as "typically" and "generally'.'

9) Applicant's arguments filed 18 August of 2003 have been fully considered but they are not persuasive.

10) Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however,

will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

11) This application contains claims 1 to 29 and 36 to 79, drawn to an invention nonelected with traverse in Paper No. 13. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John D. Ulm whose telephone number is (703) 308-4008. The examiner can normally be reached on Monday through Friday from 9:00 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached at (703) 308-6564.

Official papers filed by fax should be directed to (703) 308-4242 or (703) 872-9306. Official responses under 37 C.F.R. § 1.116 should be directed to (703) 872-9307.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.